

TYPE ABSTRACT WITHIN BOX

Pramlintide, an Analog of Human Amylin
Improves Glycemic Control in Patients with Type
II Diabetes Requiring Insulin.

ROBERT THOMPSON*¹, LEEANNE PEARSON*¹, STEVEN
SCHOENFELD*¹, ORVILLE KOLTERMAN*¹. San Diego, CA

The effects of 4 weeks of subcutaneous administration of pramlintide, (Pr) an analog of human amylin, on glycemic control in 203 patients with Type II diabetes mellitus requiring insulin were examined in a randomized, double-blind, placebo-controlled, parallel-group trial. Statistically significant reductions in serum fructosamine concentration were observed in the Pr 30 µg QID group (17.5 ± 4.9 µmol/L), the Pr 60 µg TID group (24.1 ± 4.9 µmol/L) and the Pr 60 µg QID group (22.6 ± 4.1 µmol/L) compared to placebo (PBO) (3.5 ± 3.8 µmol/L). There also were statistically significant shifts in the proportion of patients with an abnormal serum fructosamine concentration at baseline that normalized at Week 4 within the Pr 60 µg TID group (28%) and the Pr 60 µg QID group (31%) compared to PBO (10%). Consistent with the reduction in fructosamine, there were also statistically significant reductions in HbA_{1c} in the Pr 30 µg QID group ($0.53 \pm 0.07\%$), the Pr 60 µg TID group ($0.58 \pm 0.07\%$) and the Pr 60 µg QID group ($0.51 \pm 0.08\%$) compared to placebo ($0.27 \pm 0.08\%$). Based on RBC lifespan, and assuming stable glycemic control, these reductions in HbA_{1c} in the Pr groups should increase over the following 2-3 months. The reductions in fructosamine and HbA_{1c} were accompanied by a statistically significant reduction in fasting total and LDL cholesterol. In contrast to treatment with insulin alone, there were trends towards decreased body weight in the Pr 60 µg TID and 60 µg QID groups. Furthermore, the incidence of hypoglycemia was no greater in any Pr group than in placebo. In conclusion, measurement of similar changes in both serum fructosamine concentration and HbA_{1c} suggests that pramlintide therapy for 28 days improves glycemic control in patients with Type II diabetes mellitus requiring insulin.

FOR OFFICE USE ONLY

Date Rec'd _____ PMT? _____

Abstract No. _____

Duality? _____ Y _____ N Signed? _____ Y _____

Record No. _____

Mean Score _____

FORM A
(For publication)

CHECK ONE (See #21):

- ☐ Poster Session Preferred ☒ Oral Session Preferred
☐ Poster Session Only ☐ Oral Only
☐ No Preference

The author's wishes will be followed if possible.

☐ I am submitting this abstract after January 6, 1997 as "late-breaking research" (See #33).

Abstract Category Number: 14
(Categories listed on pg 4)

IMPORTANT

This form must be signed by an active member of the Professional Section of the American Diabetes Association.

The instructions on pages 1 and 2 must be followed exactly for abstracts to be considered for review.

The sponsoring member agrees that the material submitted herein conforms with instructions on pages 1 and 2.

Robert G. Thompson
MEMBER SIGNATURE

R. Thompson
PRINTED NAME

List family name, first name, middle initial, credentials/degrees, address (including city/state/country/zip), and telephone/fax numbers of author who should receive correspondence (please type or print):

Family Name ThompsonFirst Name Robert MI GCredentials/Degrees M.D. Department Clinical DevelopmentInstitution Amylin PharmaceuticalsStreet Address 9373 Towne Centre DrCity San Diego State Ca Country U.S.A. Zip Code/Postal Code 92121Phones (include area code/country/city code): Work: 619-642-7133 Fax: 619-554-1472in part, by a grant from the American Diabetes Association? Y X N

Accepted for Oral Presentation